person be sanctioned may not vote on that recommendation at the meeting;

- (g) The PRO may allow the practitioner or other person 5 working days after the meeting to provide the PRO additional relevant information that may affect its finding; and
- (h) A verbatim record must be made of the meeting and must be made available to the practitioner or other person promptly.

§1004.60 PRO finding of a violation.

- (a) On the basis of any additional information received, the PRO will affirm or modify its finding. If the PRO affirms its finding, it may suggest in writing a method for correcting the situation and a time period for corrective action. This CAP could correspond with, or be a continuation of, a prior CAP or be a new proposal based on additional information received by the PRO. If the finding has been resolved to the PRO's satisfaction, the PRO may modify its initial finding or recommendation or close the case.
- (b) The PRO must give written notice to the practitioner or other person of any action it takes as a result of the additional information received, as specified in §1004.70.
- (c) At least one member of the PRO participating in the process which resulted in a recommendation to the OIG that a practitioner or other person be sanctioned should practice in a similar geographic area, e.g. urban or rural, and at least one member of the panel must be in the same medical specialty. Both requirements can be met by a single individual. In addition, no one at the PRO who is a participant in such a finding may be in direct economic competition with, or have a substantial bias for or against, that practitioner or other person being recommended for sanction.

§ 1004.70 PRO action on final finding of a violation.

If the finding is not resolved to the PRO's satisfaction as specified in §1004.60(a), the PRO must—

- (a) Submit its report and recommendation to the OIG;
- (b) Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is

being forwarded to the OIG, advising that— $\,$

- (1) The PRO recommendation has been submitted to the OIG;
- (2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its headquarters location. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary; and
- (3) Due to the 120-day statutory requirement specified in §1004.100(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered; and
- (c) Provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when it submits a report and recommendations to the OIG with respect to a physician or other person whom the board is responsible for licensing.

§1004.80 PRO report to the OIG.

- (a) Manner of reporting. If the violation(s) identified by the PRO have not been resolved, it must submit a report and recommendation to the OIG at the field office with jurisdiction.
- (b) *Content of report.* The PRO report must include the following information—
- Identification of the practitioner or other person and, when applicable, the name of the director, administrator or owner of the entity involved;
- (2) The type of health care services involved;
- (3) A description of each failure to comply with an obligation, including specific dates, places, circumstances and other relevant facts;
 - (4) Pertinent documentary evidence;
- (5) Copies of written correspondence, including reports of conversations with the practitioner or other person regarding the violation and, if applicable, a copy of the verbatim transcript of the meeting with the practitioner or other person;
- (6) The PRO's finding that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in

§ 1004.90

a substantial number of cases or is gross and flagrant;

- (7) A case-by-case analysis and evaluation of any additional information provided by the practitioner or other person in response to the PRO's initial finding;
- (8) A copy of the CAP that was developed and documentation of the results of such plan;
- (9) The number of admissions by the practitioner or other person reviewed by the PRO during the period in which the violation(s) were identified;
- (10) The professional qualifications of the PRO's reviewers; and
- (11) The PRO's sanction recommendation.
- (c) *PRO recommendation.* The PRO must specify in its report—
 - (1) The sanction recommended;
- (2) The amount of the monetary penalty recommended, if applicable;
- (3) The period of exclusion recommended, if applicable;
- (4) The availability of alternative sources of services in the community, with supporting information; and
- (5) The county or counties in which the practitioner or other person furnishes services.

 $[60\ FR\ 63640,\ Dec.\ 12,\ 1995,\ as\ amended\ at\ 62\ FR\ 23143,\ Apr.\ 29,\ 1997]$

§ 1004.90 Basis for recommended sanction.

The PRO's specific recommendation must be based on documentation provided to the OIG showing its consideration of—

- (a) The type of offense involved;
- (b) The severity of the offense;
- (c) The deterrent value;
- (d) The practitioner's or other person's previous sanction record;
- (e) The availability of alternative sources of services in the community; and
- (f) Any other factors that the PRO considers relevant, such as the duration of the problem.

Subpart D—OIG Responsibilities

§ 1004.100 Acknowledgement and review of report.

(a) Acknowledgement. The OIG will inform the PRO of the date it received the PRO's report and recommendation.

- (b) *Review.* The OIG will review the PRO report and recommendation to determine whether—
- (1) The PRO has followed the regulatory requirements of this part; and
 - (2) A violation has occurred.
- (c) Rejection of the PRO recommendation. If the OIG decides that a sanction is not warranted, it will notify the PRO that recommended the sanction, the affected practitioner or other person, and the licensing board informed by the PRO of the sanction recommendation that the recommendation is rejected.
- (d) *Decision to sanction*. If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—
 - (1) The recommendation of the PRO;
 - (2) The type of offense;
 - (3) The severity of the offense;
- (4) The previous sanction record of the practitioner or other person;
- (5) The availability of alternative sources of services in the community;
- (6) Any prior problems the Medicare or State health care programs have had with the practitioner or other person; and
- (7) Any other matters relevant to the particular case.
- (e) Exclusion sanction. If the PRO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with §1004.110(f).
- (f) Monetary penalty. If the PRO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 1004.110 (a)–(e).

 $[60\ FR\ 63640,\ Dec.\ 12,\ 1995,\ as\ amended\ at\ 62\ FR\ 23143,\ Apr.\ 29,\ 1997]$

$\S 1004.110$ Notice of sanction.

- (a) The OIG must notify the practitioner or other person of the adverse determination and of the sanction to be imposed.
- (b) The sanction is effective 20 days from the date of the notice. Receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.
 - (c) The notice must specify—